

the Examiner in the Office Action, the Applicant realized that there is no teaching, disclosure or suggestion in the prior art for a rivet having a flexible head portion that is capable of conforming to the angle of insertion of the rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted. For the foregoing reasons, and the reasons set forth below in the discussion of the rejection of claims 19, 22, and 25-27 under 35 U.S.C. § 103 over Warren, it is believed that new claim 28 is allowable over the prior art of record.

With respect to the objection to the specification and the rejection of claims 19-27 under 35 U.S.C. § 112, first paragraph, the language of claim 19 has been amended to overcome the rejection. The language of claims 19 and 20 have further been amended to recite that the conical head of the rivet is a penetration head at the insertion end of the rivet to eliminate any confusion with the flexible member at the rear end of the rivet to which the Examiner refers to as the "head" in the Office Action. It is believed that as now amended, the objection to the specification and the rejection of claims 19-27 under 35 U.S.C. § 112, first paragraph have been overcome.

With respect to the rejection of claims 19-27 under 35 U.S.C. § 112, second paragraph, the language of claim 19 has been amended to clarify any confusion regarding the height of the projections relative to the dimensions of the heads. The language of claim 19 has been further amended to cure the lack of antecedent basis and to clarify that the largest dimension of the head as being the width of the head. With respect to the rejection of claim 24, the language of claim 24 has been amended to define the that the apex of each of the projections is measured from the central longitudinal axis of the shaft. It is believed that the rejections of claims 19-27 under 35 U.S.C. § 112, second paragraph, have been overcome.

With respect to the rejection of claims 19, 22, and 25-27 under 35 U.S.C. § 103 over Warren, the language of claim 19 recites

that the flexible member of the rivet is flexible so as to be able to deform and conform to the surface of the tissue in which the rivet is inserted as shown in Figure 4 of the Application. The flexible member of the claimed invention is also capable of conforming to the angle of insertion of the rivet into the tissue. Such structure is not taught, disclosed or suggested by Warren.

In the Warren patent, the head (110) of the rivet is not disclosed as being flexible so as to be able to deform and conform to the surface of the tissue, but forms a sharp angle with the surface of the tissue, thereby creating a projection which could result in irritation in the tissues of the joint in which the tissues are being repaired. Further, the patent to Warren only shows the perpendicular insertion of the rivet into the tissue and the head (110) in Warren is thick. There is no teaching, disclosure or suggestion that the head in Warren could be flexible to conform to the angle of insertion of the rivet into the tissue.

Moreover, the language of claim 19 of the present invention also recites the limitation that the rivet of the claimed invention has a plurality of spaced, separate, flexible projections extending radially from the hollow shaft in which at least one of the flexible projections is capable of flexing toward the shaft when being inserted in the tissue in which at least a portion of the flexible projections extends a distance from the central axis of the shaft greater than the width of the flexible member. Warren does not teach a rivet with flexible projections.

Instead Warren teaches radially projecting ribs 135 that are not flexible and are incapable of flexing toward the shaft when inserted in tissue. As there is no space between the ribs of Warren and the shaft, the ribs have no room to flex toward the shaft. Further, as can be seen in Figure 12 of Warren showing a partial cross sectional view of the ribs 135, each of the ribs 135 have a solid, wide attachment point along the longitudinal axis of the shaft. The wide attachment point of each of the ribs 135 in Warren does not permit the ribs 135 to flex so that they may be pushed through an opening that is smaller than the largest outside

dimension of the ribs.

In contradistinction, as recited in claim 19, the projections of the claimed invention are separate, flexible projections, flexing toward the shaft as they are pushed through a smaller opening in the tissue than the largest outside dimensions of the projections. In this manner, no path is cored out through soft tissue and the soft tissue is only minimally stretched. Such a feature is not taught, disclosed or suggested by Warren.

It is believed that as now amended, the rejection of claim 19 under 35 U.S.C. § 103 over Warren has been overcome. As claims 22 and 25-27 depend from claim 19, they necessarily include all of the limitations of claim 19 as now amended and are believed to be patentable distinguishable over Warren for the same reasons as claim 19.

With respect to the rejection of claims 20 and 21 under 35 U.S.C. § 103 over Warren in view of Bays et al., the language of claim 20 recites the combination of the rivet of the claimed invention and a driving means having a rod with a tapered tip which forms the same angle as the angle of the conical penetration head of the rivet to form a smooth transition from the tapered tip to the head of the rivet.

As discussed at length in the prior amendments, Bays et al. does not teach, disclose or suggest the rivet of the claimed invention. Specifically, Bays et al. does not teach, disclose or suggest the driving means of the claimed invention for inserting the rivet into the tissue. There is no disclosure or suggestion in Bays et al. for a driving means having a tapered tip which forms the same angle as the angle of the conical penetration head of the rivet to form a smooth transition from the tapered tip to the head of the rivet. Bays et al. teaches a needle 30 having a sharp end 31 having a different angle than the insertion end 12 of the tack 10 of Bays et al. Bays et al. does not teach, disclose or suggest the structure of the claimed invention. It is believed that the rejection of claim 20 under 35 U.S.C. § 103 over Warren in view of Bays et al. has been overcome.

As claim 21 depends from claim 20, it is believed that claim 21 also presents novel and non obvious subject matter over Warren in view of Bays et al. for the same reasons as claim 20. Moreover, it is believed that claim 21 is novel and non obvious over Warren in view of Bays et al. since there is no teaching, disclosure or suggestion in the references cited for a driving means having a rod portion with a length from the handle to the tapered tip is the same as the length of the rivet being inserted. The length of the rod portion is an essential feature of the claimed invention because it prevents the overpenetration of the driving means during the insertion of the rivet into the tissue. The Examiner's position that the length of the driver means is considered to be an obvious choice of experimentation and design is not justified. Such a position could only be conceived by resort to hindsight after having seen the Applicant's invention. There is not any teaching or suggestion in the prior art of any kind to permit the Examiner, in effect, to create the claimed invention by altering the components of the prior art to make the claimed invention. It is believed that the rejection of claim 21 under 35 U.S.C. § 103 over Warren in view of Bays et al. has been overcome.

With respect to the rejection of claims 23 and 24 under 35 U.S.C. § 103 over Warren in view of Duncan, claims 23 and 24 depend from claim 19 and are believed to novel and non obvious over Warren for the same reasons set forth above in the discussion of claim 19. Further, claim 23 recites that the flexible projections are positioned in a radially staggered configuration along the shaft. Claim 24, is dependent from claim 23, and further includes the limitation that each of the flexible projections has an apex measured from the central longitudinal axis of the hollow shaft, in which no more than two of the apexes are in one plane perpendicular to the longitudinal axis of said shaft at any point along the shaft. In this manner, the maximum width of the rivet of claim 24 does not exceed the sum of the apexes in order to facilitate the insertion of the rivet through an opening in the tissue in which said rivet is inserted. Such features are not taught, disclosed or

suggested by the references cited by the Examiner.

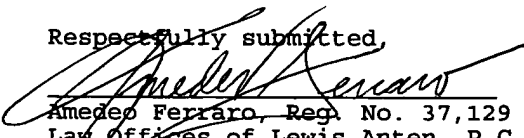
The Examiner cites Duncan as showing staggered projections. However, staggered projections are not shown or disclosed by Duncan. The projections in Duncan are uniformly aligned along the radius of the legs of the rivet. The present invention is further distinguishable over the patent to Duncan. Duncan teaches rivet having a plurality of legs with a plurality of radial projections on each leg used in association with a complementary fastener on the other side of the tissue to hold the two pieces of tissue together. In Duncan, two parts are needed to bind the tissue portions together, and not one part as recited in the claimed invention.

The Examiner's position that it would have been obvious to modify the rivet of Warren with the radially spaced projections as taught by Duncan does not result in the claimed invention and is not justified. Such a position could only be conceived by resort to hindsight after having seen the Applicant's invention. There is not any teaching or suggestion in the prior art of any kind to permit the Examiner, in effect, to create the claimed invention by altering the components of the prior art to make the claimed invention. It is believed that the rejection of claims 23 and 24 under 35 U.S.C. § 103 over Warren in view of Duncan has been overcome.

For the foregoing reasons, it believed that the claims are now in condition for allowance. A Notice of Allowance is respectfully requested. Should there be any remaining or further questions, the Examiner is requested to please contact the undersigned directly.

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Respectfully submitted,


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